



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6732

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 5, 1996

Our Reference: 2952462

Glenn H. Tanoue, President
Tropic Fish & Vegetable Center
1020 Auahi Street
Honolulu, Hawaii 96814

WARNING LETTER

Dear Mr. Tanoue:

On September 23 and 24, 1996, FDA Investigator John Cook, FDA Biologist Linda J. Cruz, and Hawaii Food & Drug Inspector Lynn Wong conducted an inspection of your seafood processing facility at 1020 Auahi Street, Honolulu, Hawaii. The inspection revealed insanitary conditions which constitute violations of the Federal Food, Drug and Cosmetic Act, and related regulations for good manufacturing practices (GMP's) which are established in Title 21, *Code of Federal Regulations*, Part 110.

A sample of swordfish, collected during the inspection, was organoleptically analyzed by FDA and found to be adulterated within the meaning of Section 402(a)(3) of the Act in that it was decomposed (Class 3).

At the conclusion of the inspection, FDA informed Ricky Takemoto, Controller, that the swordfish had been decomposed and was violative. Mr. Takemoto said that the swordfish would be destroyed. An appointment was made with FDA to witness the destruction the following day. However, when FDA arrived by appointment, it was discovered that the

decomposed swordfish had been distributed to customers. Your firm subsequently recalled the swordfish, recovering 60 of the 76 pounds distributed.

Insanitary conditions were listed on Form FDA 483 and discussed with Mr. Takemoto. A copy is attached for your review and action. Briefly, these conditions included wastewater from the rear loading dock flowing onto the facility floor where the ice machine is located; lack of a back flow prevention device on a water supply line located by the ice machine; tuna held directly on the processing floor; mold, debris and water condensate in several areas of the processing room; whole and filleted fish held directly on wooden pallets and wooden shelves; tuna and marlin held unrefrigerated in your delivery van; and a gap between the ice machine chute and the ice holding bin which could allow accumulated filth and water condensate to contaminate the ice. Other observations not listed on Form FDA 483 included the presence of flies in the processing room; the presence of live cockroaches on plastic pallets kept in the product receiving area; a lack of soap for employees in the processing room; fish debris and dried blood on the walls, shelves and floors of the walk-in refrigerator and walk-in freezer; and unpleasant sour odors emanating from the refrigerator.

Foods processed in your facility under these conditions are adulterated within the meaning of Section 402(a)(4) of the Act in that they have been prepared, packed or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Section 301(a) prohibits the introduction, or delivery for introduction, into interstate commerce of any adulterated and/or misbranded food. Section 301(c) prohibits the receipt in interstate commerce of any food that is adulterated, and the delivery or proffered delivery thereof for pay or otherwise. The adulteration of food after receipt in interstate commerce is prohibited by Section 301(k).

Similar objectionable conditions were found at your firm during an inspection in April 1996. These included a pool of bloodied and dirty water in the receiving area, due to a clogged floor drain, in contact with a pallet containing fresh tuna; a lack of backflow prevention devices on water lines; fish held without refrigeration; peeling paint, green algae, slimy residue and condensate in several areas of the processing room; presence of live flies and cockroaches in the processing room and product staging areas; and a lack of sanitizing foot baths for employees that were observed walking through a pool of dirty water while loading and unloading fish and then entering the processing facility.

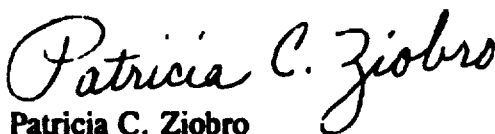
You must immediately take appropriate steps to correct the insanitary conditions at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Tropic Fish & Vegetable Center
Honolulu, Hawaii

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Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,


Patricia C. Ziobro
District Director

Attachments: Copy of FDA-483

Copy of Title 21, Code of Federal Regulations, Part 110

cc VIA CERTIFIED MAIL, RETURN RECEIPT REQUESTED

Ricky Takemoto, Controller
Tropic Fish & Vegetable Center
1020 Auahi Street
Honolulu, Hawaii 96814

Katherine K. Tanoue, Vice President
Tropic Fish & Vegetable Center
1020 Auahi Street
Honolulu, Hawaii 96814